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**S.O.S.MS PROJECT** STANDARD OUTCOME SET  
MULTIPLE SCLEROSIS

# Development of the international, multidisciplinary, patient-relevant standard outcome set for Multiple Sclerosis: the S.O.S.MS project

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# PROJECT TEAM



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Disclosure statement: KD, STFMF, PBVDN, PJVDW and EMWVDG received funding for a VBHC investigator-institution initiated research for MS from Roche Nederland B.V. Funding paid to Institution.

The project team declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this project.

# VALUE-BASED HEALTHCARE FOR MS

Currently, there is no consensus on which treatment outcomes need to be measured in Multiple Sclerosis (MS) care. Consequently, it is difficult to monitor and (inter)nationally compare real-world treatment outcomes of MS care. To encourage the shift towards **value-based MS-care**, there is need for a standard set of outcomes for MS.

The aim of this study was to develop the first international, multidisciplinary, patient-relevant standard outcome set for MS (S.O.S.MS).

But what outcomes should we measure?



# METHOD



A mixed method design including a systematic literature review, four patient focus groups (n=30) and consensus-driven RAND- modified Delphi process with an international, multidisciplinary MS expert panel. In the literature study and patient focus groups a long list of outcomes was gathered. The long list of outcomes subsequently served as input for the consensus process with the expert panel.



Literature study

Aim: to explore which outcome measures and patient characteristics are currently used to evaluate outcomes of MS care.

#### Keywords

Multiple Sclerosis, MS, Outcome Assessment, patient reported outcome, patient centered-outcome, clinical outcome, relevant outcome, outcome measure, core outcome, treatment outcome, PROM(s), PREM(s), endpoint, clinical status, quality indicator, clinical indicator, health indicator.

#### Inclusion criteria

- ✓ Diagnosed with MS
- ✓ Over 18 years old
- ✓ Articles published between 2008 - 2018
- ✓ English/Dutch language

#### Saturation method

1. Databases: PubMed, Embase, PsychINFO, grey literature
2. Total: n = 15328 references found
3. Randomly screen 200 references
4. Data extraction: outcome measures, instruments, case-mix variables, patient characteristics
5. Screen additional sets of 50 references until saturation (no new outcome measurements found)



Patient focus groups

Aim: to explore which outcome measures are important to MS patients.

#### Group discussion

- 2,5 hour
- Platform for peer support
- Heterogeneous group of MS patients
- Audiotape and notes
- N=30, divided over 4 groups

#### Study population

- ✓ > 18 years old
- ✓ Able to understand and give written informed consent
- x Additional diagnosis that overshadows the symptoms of MS
- x Inability to participate due to severity of MS symptoms

#### Topic list

- Importance of treatment outcomes
- Outcomes during first treatment choice
- Outcomes during different stages of treatment process
- Outcomes and treatment switches
- Communication about outcomes

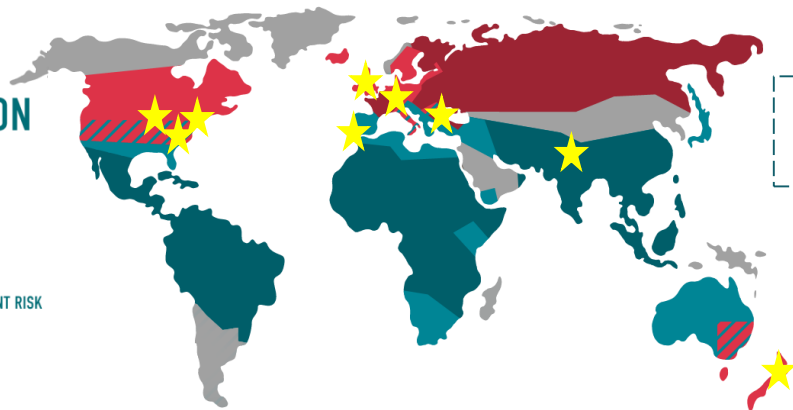


Expert panel

# S.O.S.MS Expert Panel

## GLOBAL DISTRIBUTION OF MS

- HIGH RISK
- PROBABLE HIGH RISK
- LOW RISK
- PROBABLE LOW RISK
- NORTH-SOUTH GRADIENT RISK
- OTHER RISK



## 8 countries

With high MS-prevalence

United States  
Ireland  
Portugal  
The Netherlands  
Switzerland  
Turkey  
India  
New Zealand

17  
MS-experts

## 5 disciplines

MS-nurses  
Neurologists  
Physiotherapists  
Occupational therapists  
Value-based healthcare experts

2 MS-patient representatives



Rating outcomes

Rating discussed outcomes  
Rating case-mix variables

Rating 'left over' case-mix variables  
Rating outcome measurement tools

S.O.S.MS Kick-off

Online voting round 1

Consensus 2

Online voting round 2

Consensus 3

Online voting round 3

Consensus 4 Final

Introduction  
Determine medical condition  
Determine treatment options  
Completeness of outcomes list

Discussion of rated outcomes

Discussion case-mix variables  
Discussion of final outcomes

Consensus on final standard set

**Voting arguments**

1. Frequency of outcome
2. Impact of the outcome on patient
3. Potential for modifying outcome
4. Feasibility of measuring the outcome

**Voting arguments**

1. Relevance of case-mix variable
2. Independency of case-mix variable
3. Feasibility of measuring the case-mix variable

# RESULTS: STANDARD OUTCOME SET MS

Domain	Outcomes	Outcome measurement	Timing
Disease activity	Number of new and/or active lesions	Clinical abstraction: MRI T1 and/or MRI T2	Annually
	Number of relapses per year (Annual Relapse Rate)	Clinical abstraction: dates of relapses	Ongoing
	Switch from relapsing to progressive	Clinical abstraction: date of switch	Ongoing
Functional status	Cognition	Symbol Digit Modalities Test (SDMT)	6-monthly
	Walking	Timed 25-foot walk test (T25FW)*	6-monthly
	Upper extremity function	Nine-Hole Peg Test (NHPT)	6-monthly
	Balance/Falls	Timed up and go (TUG), and number of falls	6-monthly
	Visual functioning	Low-contrast letter acuity test (LCLA) (10min)	6-monthly
Quality of Life	Bladder dysfunction	Multiple Sclerosis Impact Scale (MSIS-29)	6-monthly
	Health Related quality of life		
	Participation level in daily functioning		
	Fatigue	5-item Modified Fatigue Impact Scale (MFIS-5)	6-monthly
	Depression	9-item Patient Health Questionnaire (PHQ-9)	6-monthly
	Pain	Visual Analog Scale (VAS)	6-monthly

\* plus a note of disease steps (The Disease Steps scale consists of 0 = Normal; 1 = Mild disability, mild symptoms or signs; 2 = Moderate disability, visible abnormality of gait; 3 = Early cane, intermittent use of cane; 4 = Late cane, cane-dependent; 5 = Bilateral support; 6 = Confined to wheelchair; and U = Unclassifiable)



# RESULTS: CASE-MIX VARIABLES

Case-mix variabele	Description	Values	Timing
Age	Date of birth	Dd/mm/yyyy	At baseline - diagnosis
Sex	Sex at birth	0= male 1= female	At baseline - diagnosis
Disease duration	Date diagnosis	Dd/mm/yyyy	At baseline - diagnosis
Previously used disease modifying treatments (DMTs)	a) Type DMT b) Date start DMT	a) Name DMT b) Start date: dd/mm/yyyy	Ongoing
Currently having a relapse (vs being stable for 30 days)	Date of relapses	Dd/mm/yyyy	Ongoing
Type of MS	Type of MS at diagnosis	0=relapsing 1=progressive	At baseline - diagnosis
Baseline EDSS score	Extended Disability Status Scale	Score 1-10	At baseline - diagnosis

# CONCLUSION

With the S.O.S.MS Project, we have developed the first **international, multidisciplinary standard outcome set for MS.**

The availability of a standard set enables (inter)national measurement and comparison of patient-relevant outcomes of MS-care. Monitoring the outcomes in this standard set is a first step towards value-based healthcare for people with MS.

The standard outcome set for MS can be used for:

- Value-based quality improvement
- Benchmarking outcomes between hospitals
- (real-world) Scientific research
- Patient information
- Shared-decision making
- Contracting care

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DO YOU HAVE ANY QUESTIONS  
OR SUGGESTIONS?

PLEASE, FEEL FREE TO SEND  
ME A MESSAGE!



A big THANK YOU to

The S.O.S.MS Experts panelists

Participants of the patient focus groups

Roche Nederland B.V. for funding this project